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May 16, 2007

By Hand

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(Attn: TSCA Section 8(e) Coordinator)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Re: TSCA Section 8(e) Submission of Preliminary Results of Inhalation Studies of Acetaldehyde and Acrolein

Dear Sir or Madam:

On behalf of its member companies and in accordance with Section 8(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2607(e), the American Forest & Paper Association, Inc. ("AF&PA")[1] hereby notifies EPA of the preliminary results of sub-chronic inhalation exposure studies for acetaldehyde and acrolein.

At the request of AF&PA and other organizations, researchers at CIIT Centers for Health Research ("CIIT") have been studying the effects on rats of inhalation exposure to acetaldehyde and acrolein. Specifically, the test animals were exposed to various airborne concentrations of these chemicals for six hours a day, five days a week, for 13 weeks.

These studies are ongoing, and CIIT has developed only preliminary conclusions about observed effects. AF&PA and its members have not yet received CIIT's draft or final written report discussing the results of these inhalation studies. We are aware, however, of EPA guidance that Section 8(e) reporting may be required under certain circumstances even for preliminary study results and even for information obtained only orally. On that basis, we have concluded that some of the information reported by CIIT at an April 18, 2007 meeting with representatives of AF&PA, EPA, and others might be considered reportable under that guidance even at this preliminary stage. (Note that representatives of

[1] AF&PA is the national trade association of the forest, pulp, paper, paperboard, and wood products industry. AF&PA represents member companies engaged in the growing, harvesting, and processing of wood and wood fiber, and the manufacture of pulp, paper, and paperboard products from both virgin and recycled fiber, as well as solid wood products.

EPA's Office of Research and Development and Office of Air and Radiation were present at the April 18, 2007 meeting, and so arguably the following is information already known to the Administrator within the meaning of Section 8(e). To make sure there is no question, however, AF&PA is submitting this Section 8(e) notice for the same information that those EPA representatives obtained at the April 18, 2007 CIIT meeting.)

For acetaldehyde, CIIT found evidence of olfactory epithelial degeneration at concentrations of 150, 500, and 1500 ppm. The preliminary no observed adverse effect level (NOAEL) reported by CIIT was 50 ppm. In addition, the preliminary results reported by CIIT indicated a NOAEL for squamous metaplasia in the larynx and trachea of 150 ppm (with observed effects at the 500 and 1500 ppm concentrations).

For acrolein, CIIT presented preliminary conclusions that inhalation exposure produced squamous metaplasia in the larynx, with a NOAEL of 0.6 ppm (with observed effects at the 1.8 ppm dose). CIIT also reported preliminary results finding nasal respiratory epithelial degeneration in rats exposed to acrolein, with a NOAEL of 0.2 ppm (observed effects at 0.6 and 1.8 ppm), and olfactory epithelial degeneration, with a NOAEL of 0.6 ppm.

AF&PA intends to follow this Section 8(e) report of preliminary results with submission to EPA of the final reports that will be prepared for the CIIT inhalation studies.

Current and historical EPA guidance interpreting TSCA Section 8(e) directs persons to report information with relatively little assessment of the strength of the information or its potential value for risk assessment or other purposes. Our submittal of this information under Section 8(e) does not imply in any way that the information indicates an actual adverse effect from a particular chemical substance or mixture or an actual risk to human health, either past or present.

In fact, CIIT has also performed a preliminary derivation of a health benchmark for human exposure, based on the most sensitive endpoint in its study of inhalation exposure to acetaldehyde and using a hybrid physiologically based pharmacokinetic (PBPK)/ computational fluid dynamic (CFD) model and applying safety factors. That preliminary health benchmark is 90-fold higher (i.e. less stringent) than EPA's Reference Concentration (RfC) for non-cancer effects of acetaldehyde. Thus, based on preliminary information, AF&PA believes that the overall conclusion of the work CIIT is doing on acetaldehyde will be that acetaldehyde presents a significantly lower inhalation risk to humans than EPA previously believed. CIIT is performing similar modeling using the most sensitive endpoint in its inhalation study of acrolein, but preliminary results of that modeling are not yet available.

No claim of confidentiality for information contained in this submission is made, either under TSCA Section 14(c) or any other provision.

If you have any questions regarding this notification, please contact me at the above address or call me at (202) 463-2777.

Sincerely,

Lori A. Perine
Executive Director, Policy Analysis & Research
and Agenda 2020 Technology Alliance

Attachments
cc: AF&PA Member Companies